REMARKS

Claims 1-22 have been presented for examination and remain currently pending. Of these claims, claims 1, 8, 21 and 22 have been amended to clarify that the claimed distillation process enriches the content of desirable cis-9,trans-11(c9,t11) and trans-10,cis-12 (t10,c12) CLA isomers. Support for the amendment may be found, for example, at Par. 0056 and 0069. Thus, the amendments do not add new matter. Claims 1-7 and 21-22 have been rejected under 35 USC §102(b) as being anticipated by Strube et al., U.S. Patent No. 6,762,313 ("Strube"). Claims 8-20 have been rejected under 35 USC §103(a) as being unpatentable over Saebo et al., U.S. Patent No. 6,743,931 ("Saebo"), Baltes et al., U.S. Patent No. 3,162,658 ("Baltes") and Strube. No claim has been allowed.

Reconsideration of the Examiner's rejection of the claims in view of the amendments and the following remarks is respectfully requested.

The Claimed Subject Matter

The present claims are directed to a process of distilling an ester stream containing conjugated linoleic acid esters to increase the content of the conjugated linoleic acid esters in the ester stream. In addition, the distillation process removes side products formed during the conjugation process.

Previously, it was believed that conjugated linoleic methyl esters were too thermally unstable to be distilled. For example, Example 19 of U.S. Patent No. 6,420,577 sets forth a distillation process that "was not an appropriate method of

refining CLA" because large amounts of undesirable CLA by-products of unknown biological activity were formed during the distillation. The thermal instability of conjugated linoleic methyl esters compared to methyl linoleates is further demonstrated in the present application in Examples 3 and 4. Example 3 of the present application shows that methyl linoleates (i.e., unconjugated linoleic methyl esters) are substantially stable when exposed to a temperature of 200° C under nitrogen for 50 hours. However, Example 4 of the present application shows that conjugated linoleic acid esters are not thermally stable. After only 77 minutes at a temperature of 195° C, the amount of c11,t13, an undesirable isomer of conjugated linoleic methyl ester, grew from undetectable levels to 2.3% of the composition. These results demonstrate that conjugated linoleic acid esters undergo thermal rearrangement when exposed to high temperatures, whereas similarly exposing nonconjugated linoleic acid esters to such high temperatures does not cause thermal rearrangement. In view of the prior art teachings that distillation of conjugated linoleic acid is not appropriate, and the fact that conjugated linoleic acid esters have very different thermal stabilities when compared to unconjugated linoleic acid esters, distillation of conjugated linoleic acid esters was not previously considered to be possible.

Surprisingly, applicants have discovered that conjugated linoleic acid esters can be distilled under certain conditions that allow the desirable isomers of conjugated linoleic acid esters to be increased, while minimizing the formation of undesirable side products and rearrangement of undesirable isomers.

Rejection Under §102(b) Based on Strube

According to the Office Action, Strube discloses a distillation process wherein a transesterification reaction mixture containing esters of linoleic acid is distilled to increase the linoleic acid content. Example 1 and Table 1 in column 4 of the Strube reference are cited for allegedly showing that the Strube process produces a composition enriched with conjugated linoleic acid esters while removing unconjugated linoleic acid compounds.

The Strube process, however, involves distilling a mixture containing unconjugated linoleic acid esters to increase the content of unconjugated linoleic acid esters. None of the isomers listed in Table 1 of column 4, showing the fractions resulting from the Strube distillation, is a conjugated linoleic acid. This is evident from a review of the information contained in a table from "Fats and Fatty Oils," Kirk-Othmer *Encyclopedia of Chemical Technology*, 4th Ed. Vol. 10, 1993, which is attached to this amendment as Exhibit 1. This table provides the common names and chemical designations for fatty acids found in naturally occurring triglycerides. As is clear from reviewing the information in this Table, the c16:0 isomer listed in Table 1 at col. 4 of the Strube patent is palmitic acid, c18:0 is stearic acid, not unconjugated linoleic acid, as the Examiner has suggested, c18:1 c9 is oleic acid having a cis double bond at the 9th carbon in the chain, and c18:2 c9,c12 is linoleic acid having cis double bonds at the 9th and 12 carbons, i.e., a nonconjugated linoleic acid. From a comparison of the nomenclature provided in the table of the Kirk-Othmer *Encyclopedia of Chemical Technology* and the data in Table 1 of Strube, it is clear that Strube merely discloses a

distillation process that increases the content of ordinary linoleic acid, i.e., c9,c12 linoleic acid. The resulting product is a linoleic acid rich material that must be subsequently isomerized to produce the desirable 9cis, 11 trans and 10 trans, 12cis conjugated linoleic acid isomers. See, e.g., title of the Strube patent and col. 2, lines 5-14. By contrast, present claims 1-7 and 21, 22 specify distilling a first ester stream containing esters of conjugated linoleic acids. Distillation of already prepared conjugated linoleic acids is nowhere disclosed in the Strube patent as required by the present claims. Because Strube does not disclose the process steps recited in present claims 1-7, and does not disclose a composition enriched in conjugated linoleic acids, as recited in claims 21 and 22, Strube cannot anticipate those claims under 35 USC §102(b). Accordingly, applicants respectfully request that the rejection under 102(b) be withdrawn.

Rejection Under 35 USC 103(a) Based on Saebo, Baltes and Strube

Claims 8-20 have been rejected as being unpatentable over Saebo, Baltes and Strube. Saebo and Baltes merely disclose processes for the preparation of conjugated linoleic acids. Neither reference discloses distillation of conjugated linoleic acids, as required by claims 8-20. Moreover, as explained above, Strube also does not disclose distillation of conjugated linoleic acids. Accordingly, even if the references are combined, as proposed by the Examiner, the combination does not disclose or render obvious the process claimed in claims 8-20 because none of the references discloses or suggests the step of distilling conjugated linoleic acids.

According to the Examiner, it would have been obvious to one of ordinary skill in the art to add a distillation step after isomerization "to further tweak the steps in order to increase the purity." Such an assertion, however, is completely without support from any reference, is contrary to the prior art teachings that "[d]istillation was not an appropriate method of refining CLA." (See U.S. 6,420,577 at col. 8, lines 6-8), and fails to take into account that unconjugated linoleic acids are thermally stable, whereas conjugated linoleic acids are not and undergo rearrangement. Accordingly, in view of the teachings of the '577 patent and the fact that conjugated linoleic acids are thermally unstable and undergo rearrangement, one of skill in the art would not have been motivated to distill conjugated linoleic acid because of the likely formation of undesirable CLAs during the distillation process.

For all of the above reasons, it is submitted that all of the claim rejections have been overcome. Favorable reconsideration of the application and allowance of the claims are therefore respectfully requested.

The Commissioner is authorized to charge any necessary fees or credit any overpayment to Deposit Account No. 13-0017 in the name of McAndrews, Held & Malloy, Ltd.

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Respectfully submitted,

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